

**POLYMER-BASED ORTHOPEDIC SCREW AND DRIVER
SYSTEM WITH INCREASED INSERTION TORQUE TOLERANCE
AND ASSOCIATED METHOD FOR MAKING AND USING SAME**

Field of the Invention

The present invention relates to orthopedic screws and screw drivers and more particularly to cannulated screws and screws with an internal bore having a polymer component and methods for making and using same.

Background of the Invention

Medical screws of various designs and material composition are used to affix medical implants, grafts and bone fragments to substrate bone structures during orthopedic surgery. One surgical use involves insertion of an interference screw into a bone tunnel to secure an end of an anterior cruciate ligament (ACL) replacement graft in place. ACL reconstruction procedures and interference screws are disclosed, e.g., in U.S. Patent Nos. 5,062,843, 4,950,270 and 4,927,421.

Medical screws have typically been fabricated from medically approved metallic materials, such as stainless steel or titanium, which are not absorbed by the body. Screws made of these strong materials exhibit sufficient torsional strength to withstand the torque necessary to insert the screw into bone. A disadvantage of such screws, however, is that once healing is complete, an additional surgical procedure may be required to remove the screw from the patient. Metallic screws may include a threaded shank joined to an enlarged head having a transverse slot or hexagonal socket formed therein to engage, respectively, a similarly configured, single blade or hexagonal rotatable driver for turning the screw into the bone. The enlarged heads on such screws can protrude from the bone tunnel and can cause chronic irritation and inflammation of surrounding body tissue.

Permanent metallic medical screws in movable joints can, in certain instances, cause abrading of ligaments during normal motion of the joint. Metallic screws also occasionally back out after insertion, protruding into surrounding tissue and causing discomfort. Furthermore, permanent metallic

screws and fixation devices may shield the bone from beneficial stresses after healing. It has been shown that moderate periodic stress on bone tissue, such as the stress produced by exercise, helps to prevent decalcification of the bone. Under some conditions, the stress shielding which results from the long term use of metal bone fixation devices can lead to osteoporosis.

Biodegradable or bioabsorbable interference screws have been proposed to avoid the necessity of surgical removal after healing. Because the degradation of a biodegradable screw occurs over a period of time, support load is transferred gradually to the bone as it heals. This reduces potential stress shielding effects. Conventional bioabsorbable interference screws commonly have a polymer component and are softer and weaker than metallic screws, such that they are not self-tapping, requiring the hole drilled into the bone to receive the screw to be tapped (threaded). The necessity to tap holes in the injured bone adds to the complexity of the surgical procedure and lengthens the time required to complete the operation.

In addition, screws having a polymer component, hereinafter referred to as "polymer screws" exhibit substantially lower torsional strength than conventional metal screws, making them susceptible to deformation when subjected to the torsional loads required to drive the screw into relatively hard tissue such as bone. The high torque that must be applied to medical screws by a driver can cause shear deformation of the relatively soft polymeric material, causing damage to the screw, e.g., the driver can "strip" the recess or slot provided on the screw for the driver. If the screw is not inserted in bone to the proper depth at the point of the failure, difficulty may arise in driving the screw further in, or backing the screw out.

A number of approaches have been used to alleviate the shear deformation of polymer medical screws including low friction coatings, internal reinforcement with fibers or composite formations, crystalline orientation via subjection to compression and screw head design. In yet another approach, as shown in U.S. Pat. No. 5,169,400 (to Muhling, et al.), U.S. Pat. No. 5,470,334 and EP 0502698A1 (to Ross, et al.), and U.S. Pat. No. 5,695,497 (to Stahelin, et al.), a central cannula or recess having a non-circular cross-section running a portion of or the entire length of the screw is provided. The noncircular cross-section is disclosed as being of various shapes (hexagonal, square, star-

shaped, etc. in cross-section, or with a plurality of radial force or lobe members) with a complementarily shaped screwdriver bit to increase torque transfer. Manufacturing tolerances for forming the cannula/bore of the screw and its mating bit limit the amount of surface-to-surface contact between the cannula/bore and bit. Decreased surface-to-surface contact may result in higher stresses and an increased risk of torque failure.

This limitation is not overcome by the approach shown in U.S. Pat. No. 5,584,836 (to Ballintyn, et al.), of using a plurality of cannulae. Multiple cannula and mating driver projections are weaker than a single projection, add manufacturing complexity, and are still subject to manufacturing tolerances. This is especially an issue when complicated geometries are employed. Greater surface-to-surface contact at the driver/screw cannula interface distributes the forces exerted on the screw by the driver, reducing localized stresses and enabling a higher torque to be applied to the driver before the strength limit of the screw material is reached. Efforts to reduce manufacturing tolerances on mating parts can be cost prohibitive and time consuming to both manufacture and inspect.

Accordingly, it would be advantageous to provide a polymeric-based, cannulated medical screw or medical screw with a tool receiving bore and associated driver, wherein the outer surface of the driver and the cannula/bore surface are closely mated to increase the insertion torque tolerance of the screw.

Summary of the Invention

The limitation of prior art orthopedic screw and driver systems are remedied by the present invention which includes an elongated screw having external threads and an internal bore extending through the screw at least a portion of its length. The screw is made at least partially of a bioabsorbable material. The system includes an elongated driver having a non-circular cross-sectional shape approximating the cross-sectional shape of the screw bore. The driver is insertable into the bore and is matingly received therein to transfer rotational motion of the driver to the screw. The bore exhibits a closely mating shrink-fit relative to the driver.

A method of the present invention for increasing driver-to-screw contact includes the steps of inserting the driver into the bore of the screw; heating the screw; and allowing the screw to cool. The steps of heating and cooling inducing the screw to shrink, whereby the bore exhibits a closely mating shrink-fit relative to the driver.

Brief Description of the Figures

Figure 1 is a perspective view of a driver and screw combination in accordance with an embodiment of the present invention.

Figure 2 is another perspective view of the driver and screw combination of Figure 1.

Figure 3 is an elevational view of the driver and screw combination of Figures 1 and 2 with the driver inserted into the screw.

Figure 4 is a partially cross-sectional view of the driver and screw of Figure 3 taken along section line IV - IV and looking in the direction of the arrows.

Figure 5 is a partially cross-sectional view like that of Figure 4, but of an alternative embodiment of the present invention.

Detailed Description of the Invention

The present invention relates to an orthopedic screw and driver system and method for making and using same. A polymeric-based cannulated medical screw or a screw with a tool-receiving bore is placed on a driver with the driver extending into the cannula/bore. The assembly is then subjected to a heat treatment process wherein the cannula/bore of the screw shrinks and molds itself to the driver, thus creating a mating interface both longitudinally and circumferentially thus minimizing dimensional variations between mating parts. The screw is driven into the selected substrate and the driver removed from the cannula/bore thereof. The mating of the driver to the

screw cannula/bore increases the insertion torque tolerance of the screw. The present invention, therefore, allows cannulated screws or screws with tool bores composed mainly of bioabsorbable, polymeric materials to be inserted into bone with a decreased risk of shear deformation of the screw caused by the torque required to drive the screw into bone.

Referring to Figures 1 through 4, driver 10 is an elongated, generally hexagonal tool used for turning screw 12. Screw 12 is generally cylindrical in shape and has a plurality of external threads 14, a subset of which are lead-in or starter threads 14_L that assist the screw 12 in threading into a pilot hole drilled in the substrate, e.g., bone. The screw 12 may also be conically tapered toward the tip 24 to aid in its introduction into a substrate. While the taper shown extends only a short distance from the tip 24, a longer taper may be employed, e.g., extending half or the entire length of the screw 12, with the angle and length of taper depending upon the application. The screw 12 has an axial bore 16 which is generally hexagonal in shape to matingly receive the driver 10 therein. The bore 16 does not extend through the entire length of the screw 12. Alternatively, the bore 16 may extend through the entire length of the screw 12. The driver 10 and bore 16 may be other shapes, including, but not limited to, polygonal, cross, star, or oval shapes. Driver 10 is preferably tapered down from the proximal end 20 to the distal end 18 for easier removal of the driver 10 from the screw 12 after it is inserted into a substrate. Proximal end 20 of driver 10 may be received in a chuck or snap-fit recess of a handle, wrench or electric power tool (now shown) to facilitate turning the screw 12. A short driver 10 is depicted for ease of illustration, but any length may be employed to provide proper access to the insertion site.

As shown in Figures 2 and 4, the screw 12 may have a guide wire cannula 22 through which a guide wire (not shown) may be inserted for the purpose of guiding the screw 12 into position, e.g., during arthroscopic surgery.

In a similar manner, the driver 10 may be cannulated for the placement of a guide wire therethrough. As shown in Figure 4, the bore 16 extends almost the entire length of the screw 12 and terminates near the tip 24. Bore 16 preferably has a matching taper to that of the driver 12, with both converging in a distal direction, to enhance driver-to-bore (screw) contact and to promote easier

removal of the driver 10 from the bore 16. Preferably, the driver 10 has a friction fit relative to the bore 16, with the driver 10 extending substantially the entire length of the bore 16 when inserted therein, as shown in Figure 4. It is preferred to maximize the driver-to-screw contact to distribute the insertion forces and avoid shear failure. Figure 5 shows an alternative embodiment of the present invention wherein the driver 110 and bore 116 have a generally square cross-sectional shape, but is otherwise the same invention as that shown in Figures 1-4, like elements being labeled by reference numbers increased by 100.

The manufacturing processes used to make the bore 16, 116 of the screw 12, 112 and the driver 10, 110, whether by machining or molding, inherently involve dimensional tolerances. As a consequence, the mating surface areas of the screw 12, 112 and driver 10, 110 vary over a range due to normal dimensional variation of each of these parts. In the case of mating tapered parts, such as a tapered driver 10 and tapered bore 16, several dimensions including those for tapered angle and length, and cross-sectional geometry, each have this inherent variation due to manufacturing.

Tolerance stack up analyses can be used to give a theoretical depiction of how these tolerance variations can affect the relative surface-to-surface contact area. At one extreme, when an undersized driver 10 is mated with an oversized bore 16, the driver 10 reaches its maximum depth within the bore 16. At the other extreme, when an oversized driver 10 is inserted into an undersized bore 16, the driver 10 only inserts partially and establishes a ring or line of relative contact. Given manufacturing tolerances, it would be rare to achieve full surface-to-surface contact at the driver 10 and bore 16 interface both circumferentially and longitudinally.

In accordance with the present invention, driver-to-screw contact can be maximized through a heat treatment performed on the polymeric-based cannulated screw 12 after insertion of driver 10. More particularly, the heat treatment induces dimensional shrinkage of the screw 12 so that the screw 12 closely grips the driver 10, maximizing driver-to-screw contact. The heat treatment process can be either a one step or multi-step process depending on the mechanisms that are involved in the heat treatment. In general, the driver 10 is inserted into bore 16 of screw 12 and both are exposed to heating to a temperature that is above the glass transition temperature (preferably 5 to 15

°C above the glass transition temperature) and below the melting temperature of screw 12 for a period of time. The mechanisms that can be utilized to induce the dimensional shrinkage are: (1) relaxation of internal stresses, (which, for example, can be produced due to injection molding); or (2) crystallization of the polymer material from which the screw 12 is made.

Suitable materials from which the driver 10 may be formed are typically, but not limited to, medically approved metallic materials, such as, stainless steel, titanium alloys thereof or other medically approved materials that do not plastically deform at the temperatures used to heat treat the polymeric-based medical screw 12.

The screw 12 can be made of any biocompatible or absorbable polymer, copolymer, or blend, provided heat treatment results in dimensional changes either through relaxation and/or crystallization in the material. Suitable materials from which the screw 12 may be formed include biocompatible polymers selected from the group consisting of aliphatic polyesters, polyorthoesters, polyanhydrides, polycarbonates, polyurethanes, polyamides and polyalkylene oxides.

In the preferred embodiment, the screw 12 is made from aliphatic polymers and copolymer polyesters and blends thereof. The aliphatic polyesters are typically synthesized in a ring opening polymerization. The aliphatic polyesters are typically synthesized in a ring opening polymerization. Suitable monomers include but are not limited to lactic acid, lactide (including L-, D-, meso and D,L mixtures), glycolic acid, glycolide, ϵ -caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), δ -valerolactone, β -butyrolactone, ϵ -decalactone, 2,5-diketomorpholine, pivalolactone, α,α -diethylpropiolactone, ethylene carbonate, ethylene oxalate, 3-methyl-1,4-dioxane-2,5-dione, 3,3-diethyl-1,4-dioxan-2,5-dione, gamma-butyrolactone, 1,4-dioxepan-2-one, 1,5-dioxepan-2-one, 6,6-dimethyl-dioxepan-2-one, 6,8-dioxabicyclooctane-7-one and combinations thereof. These monomers generally are polymerized in the presence of an organometallic catalyst and an initiator at elevated temperatures. The organometallic catalyst is preferably tin based, e.g., stannous octoate, and is present in the monomer mixture at a molar ratio of monomer to catalyst ranging from about 10,000/1 to

about 100,000/1. The initiator is typically an alkanol (including diols and polyols), a glycol, a hydroxyacid, or an amine, and is present in the monomer mixture at a molar ratio of monomer to initiator ranging from about 100/1 to about 5000/1. The polymerization typically is carried out at a temperature range from about 80°C to about 240°C, preferably from about 100°C to about 220°C, until the desired molecular weight and viscosity are achieved.

The screw 12 of the present invention can also be formed from polymeric composite materials reinforced with absorbable or biocompatible glasses or ceramics including phosphates such as hydroxyapatite, substituted apatites, tetracalcium phosphate, alpha- and beta-tricalcium phosphate, octacalcium phosphate, brushite, monetite, metaphosphates, pyrophosphates, phosphate glasses, carbonates, sulfates and oxides of calcium and magnesium. These reinforcements can be in the form of particles, whiskers, platelets, fibers and the like.

Examples

The invention is further illustrated by the following non-limiting examples.

Example 1:

An 15/85 (vol/vol) blend of beta-tricalcium phosphate (β -TCP, sold by CAM Implants bv, Leiden, Netherlands) and poly(L-lactic acid) (PLA, sold by Purac Biochem, Gorinchem bv, Netherlands, with an Inherent Viscosity of 2.3 dl/g when measured in CHCl_3 at a temperature of 25°C and a concentration of 0.1 gm/dl) was compounded on a twin-screw extruder. Screws similar to the polymer-based medical screw sold under the tradename ABSOLUTE (Mitek Products, Norwood, MA) were formed on an injection molder (Model NN35MI Super Mils 4000, Niigata Engineering Company, Ltd., Itaska, IL) from the β -TCP/PLA blend. The screws were approximately 25-mm in **(length)** and 7-mm in **(diameter)**. Differential scanning calorimetry (Model 2920, TA Instruments, New Castle, DE) was performed on the unannealed screws to determine the percent crystallinity of the polymer. The polymer was amorphous.

Example 2:

Ten screws from Example 1 were placed onto stainless steel drivers obtained from Mitek Norwood, Massachusetts and were annealed (Model AGC-3366 MP2 inert gas oven with PRO-STAR controller, Blue M a unit of General Signal, Nanuet, New York) in a nitrogen environment. The annealing cycle was: room temperature to 70°C at a heating rate of 1°C/min, hold at 70°C for 4 hrs, and cool to room temperature at ~1°C/min. Differential scanning calorimetry, as discussed in Example 1, was performed on the screws annealed to determine the percent crystallinity of the polymer. As in Example 1, the polymer was amorphous.

Example 3:

Sixteen screws from Example 1 were placed onto stainless steel drivers and annealed as discussed in Example 2, but under a modified annealing cycle. For these screws, the modified annealing cycle was: room temperature to 70°C at a heating rate of 1°C/min, hold at 70°C for 4 hrs, heat to 100°C at a heating rate of 1°C/min, hold at 100°C for 8 hours, and cool to room temperature at ~1°C/min. Differential scanning calorimetry, as discussed in Example 1, was performed on these screws annealed with the modified cycle to determine the percent crystallinity of the polymer. In this case, the screws showed a crystallinity of 48 percent.

Testing of Examples 1, 2 and 3

Torque to strip tests were performed on screws from Examples 1 through 3. Different screw and driver combinations/configurations were tested to determine the factors resulting in torque strip improvement. These configurations are summarized in Table 1 and identified by sample set ID letters A-F. Screws from Example 1 (sample set F) were loaded onto randomly picked drivers. Screws from Example 2 were tested on the drivers on which they were annealed in two configurations: a screw and driver combination was either tested as taken from the annealing oven (sample set D), or removed from and then reloaded on to the same driver in its previous orientation (sample set E). Screws from Example 3 were tested in three configurations: on the

drivers on which they were annealed, either as taken from the annealing oven (sample set B), or first removed from and then reloaded on to the same driver (sample set A), or removed from the annealing driver and loaded onto another, randomly picked driver (sample set C).

Torque testing of the foregoing configurations was performed using one-inch blocks of acetal resin, sold under the tradename DELRIN by E.I. du Pont de Nemours and Company, Wilmington, DE. The DELRIN blocks were drilled with a 5 mm pilot hole and tapped with a 7 mm tap. The screws identified in Table 1 were inserted into the tapped hole until stripping occurred at the driver-screw interface. The DELRIN block was secured to the base of the mechanical testing machine (MTS, 858 Mini Bionix with the following software: TestWare-SX version 4.0C and TestStar version 4.0D, MTS Systems Corporation, Eden Prairie, Minnesota) while the proximal end of the driver was attached to the torque load cell with a set screw. Each screw was torqued at a rate of 10 deg/sec. The average torque at failure is shown in Table 2.

Torque tests were performed comparing specific sample sets to determine whether or not a statistical difference was observed at a confidence level greater than or equal to 95%. The tests show that both heat treatment methods of Examples 2 and 3 resulted in statistical improvements in the torque to failure values compared to the unannealed screws (i.e., the failure torque of configurations A, B, D and E are statistically different than configuration F), but only when testing was performed using the same driver used during annealing. These results indicate that the process of crystallization in and of itself does not improve the torque to failure, in that the crystallized screws were statistically the same as the unannealed screws when removed from the driver after annealing and tested to torque failure using randomly chosen drivers (i.e., sample sets C and F are statistically the same). However, if the screw was removed and reloaded on the same driver with the same orientation as when annealing took place, the improvement in torque to failure values is maintained. The important factor in improving torque to failure is increasing the surface-to-surface contact area between the screw and the driver. This can be accomplished both through stress relaxation (e.g. 70°C treatment of Example

2) which is applicable to both amorphous and crystallizable polymers and to a greater degree through crystallization (e.g., the 100°C treatment of Example 3).

Table 1: Testing configurations between annealed and unannealed (as-molded) screws and drivers.

Sample Set ID	Annealing Conditions [T(°C)/t(hrs.)]	Screw-Driver Configuration
A	<u>100/8</u>	Removed & reloaded onto same driver
B	<u>100/8</u>	Left on annealing driver
C	<u>100/8</u>	Removed & reloaded onto random driver
D	<u>70/4</u>	Left on annealing driver
E	<u>70/4</u>	Removed & reloaded onto same driver
F	As-molded	Loaded onto random driver

Table 2: Torque to failure testing results and statistics for annealed and unannealed (as-molded) screws

Sample Set ID	Average Torque (in-lb)	Standard Deviation (in-lb)	Sample Set Size
A	93.9	15.2	6
B	93.6	7.9	5
C	61.0	5.1	5
D	68.4	8.2	6
E	71.5	13.3	4
F	60.2	7.1	5

It will be understood by those of skill in the art that numerous and various modifications can be made without departing from the spirit of the present invention and that the embodiments of the present invention described herein

are illustrative only and are not intended to limit the scope of the present invention.